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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,543	06/03/2005	Nigel K.H. Slater	620-366	4805

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EXAMINER	
MAKAR, KIMBERLY A	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 08/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/537,543	SLATER ET AL.	
	Examiner	Art Unit	
	Kimberly A. Makar	1636	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 June 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *153-194* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *153-194* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 153-190, drawn to a method of delivering a payload into the nucleus of a living cell comprising contacting the cell with a hypercoiling carrier polymer, wherein hypercoiling polymer has both hydrophobic and hydrophilic regions.

Group II, claim(s) 191, drawn to a method of treatment of a condition to a patient comprising the administration of a hypercoiling polymer which incorporates a payload.

Group III, claim(s) 192, drawn to a method of diagnosis of a condition comprising the administration of a hypercoiling polymer which incorporates a payload, detecting a detectable label, and correlating the presence of the label with said condition.

Group IV, claim(s) 193, drawn to a method of imaging a cell comprising contacting a cell with a hypercoiling polymer which incorporates a payload, detecting the presence of a detectable label, and forming an image of the cell.

Group V, claim(s) 194, drawn to drawn to a method of imaging a patient comprising the administration of a hypercoiling polymer which incorporates a payload, detecting the presence of a detectable label and forming an image of said patient.

2. The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The invention lacks novelty. Monahan et al (US patent application publication US2003/0199090 A1) teaches a method of gene therapy delivering nucleic acids to cells utilizing monomers, polymers and co-polymers containing both hydrophobic and hydrophilic regions (see page 6-7 and page 13, paragraph 0104). Monahan teaches that the polymers can be

targeted to specific tissues, cells and intracellular compartments, including the nucleus (page 14, paragraph 1026).

3. The technical feature of Group I is a method of delivering a payload into the nucleus of a living cell comprising contacting the cell with a hypercoiling carrier polymer, wherein hypercoiling polymer has both hydrophobic and hydrophilic regions. The technical feature of group II is a method of treatment of a condition comprising the administration of a hypercoiling polymer which incorporates a payload. Group I is distinct from Group II in that the methodology of Group I differs in scope compared to the methodology of Group II. Group II encompasses cells in a patient, and therefore will require additional steps, reagents, and concentrations, dosages and conditions when compared to the method of Group I. Group I can encompass any living cell, including immortalized cells in cultures. These cells can be used in other experiments, not involved with the condition of Group II. Thus Group I and Group II are compositionally, functionally and biologically distinct and capable of supporting individual patents.

4. The technical feature of Group I is a method of delivering a payload into the nucleus of a living cell comprising contacting the cell with a hypercoiling carrier polymer, wherein hypercoiling polymer has both hydrophobic and hydrophilic regions. The technical feature of group III is a method of diagnosis of a condition comprising the administration of a hypercoiling polymer which incorporates a payload, detecting a detectable label, and correlating the presence of the label with said condition. Group I is distinct from Group III in that the methodology of Group I differs in scope compared to the methodology of Group III. Group III involves additional reagents, equipment and experimentation compared to Group I. Thus Group I and Group III are compositionally, functionally and biologically distinct and capable of supporting individual patents.

5. The technical feature of Group I is a method of delivering a payload into the nucleus of a living cell comprising contacting the cell with a hypercoiling carrier polymer, wherein hypercoiling polymer has both hydrophobic and hydrophilic regions. The technical feature of Group IV is a method of imaging a cell comprising contacting a cell with a hypercoiling polymer which incorporates a payload, detecting the presence of a detectable label, and forming an image of the cell. Group I is distinct from Group IV in that the methodology of Group I differs in scope compared to the methodology of Group IV. Group IV involves additional reagents, equipment (ie microscopes, cameras etc) and experimentation (how much time passes before the signal is seen?) when compared to Group I. Thus Group I and Group IV are compositionally, functionally and biologically distinct and capable of supporting individual patents.

6. The technical feature of Group I is a method of delivering a payload into the nucleus of a living cell comprising contacting the cell with a hypercoiling carrier polymer, wherein hypercoiling polymer has both hydrophobic and hydrophilic regions. The technical feature of Group V is a method of imaging a patient comprising the administration of a hypercoiling polymer which incorporates a payload, detecting the

presence of a detectable label and forming an image of said patient. Group I is distinct from Group V in that the methodology of Group I differs in scope compared to the methodology of Group V. Group V involves additional reagents, equipment (ie MRI? Autoradiography?) and experimentation when compared to Group I. Thus Group I and Group V are compositionally, functionally and biologically distinct and capable of supporting individual patents.

7. Groups II-V are all individual inventions encompassing methodologies that differ in reagents, and scope. Group II involves treating the cells of a patient, whereas Group III is a method of diagnosing a condition, Group IV is the methodology for imaging a cell and Group V is imaging a cell in a patient. These methodologies differ in procedure, reagents, conditions, timing etc and can be performed without the methodologies of the other groups. Group III is a method of diagnosing a condition whereas Group IV is the methodology for imaging a cell and Group V is imaging a cell in a patient. These methodologies differ in procedure, reagents, conditions, timing etc and can be performed without the methodologies of the other groups. Group IV is the methodology for imaging a cell whereas Group V is imaging a cell in a patient. These methodologies differ in procedure, reagents, conditions, timing etc and can be performed without the methodologies of the other groups.

8. Thus Groups I-IV are compositionally, functionally and biologically distinct and capable of supporting individual patents.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of

record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly A. Makar, Ph.D. whose telephone number is 571-272-4139. The examiner can normally be reached on 8AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KAM/08/04/06

DAVID GUZO
PRIMARY EXAMINER